William Paterson University
Institutional Review Board for Human Subject Research

Policy on Human Subject Research at William Paterson University

All correspondence and inquiries related to research involving human subjects may be directed to the IRB Chairperson:

Chairperson, Institutional Review Board
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300 Pompton Road, Wayne, NJ 07470

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Contact Information

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Dr. Dorothy Feola, College of Education	1999-2005
Dr. Katherine Makarec, College of Humanities & Social Science	1999-2005
Dr. Peter Mandik, College of Humanities & Social Science	2003-2006
Dr. Karen Swanson, College of Science & Health	2004-2007
Dr. Joanna Hayden, College of Science & Health	2004-2007
College of Arts & Communication	Open
Rev. Dennis TeBeest, Outside Member	2002-2005
Outside Member	Open
Dr. Nina Jemmott, Graduate Studies & Research	ex officio
Mr. Martin Williams, Office of Sponsored Programs	ex officio

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INTRODUCTION

In the period following the adoption of William Paterson University's first policy concerning the use of human subjects in research in 1996 and the initiation of the Institutional Review Board Committee in 1997 through to the preparation of this policy, over 600 protocols were reviewed and approved, the Committee met over 30 times, seminars and workshops were held on the inclusion of student research (1999), presentations were made to faculty and student groups, and many conversations took place concerning the scope, clarity and completeness of the policy. Precedents were established. Practices were developed. Interpretations were defined. New Federal regulations were enacted following public outcries and debates on the conduct of human subject research at other institutions. In short, much has been learned.

This much revised and renamed policy is a response to what the Committee has learned, the new Federal regulations, and the desire to continue the IRB's role as a positive and nurturing supporter of research at William Paterson University.

INTRODUCTION to the 1996 Policy

William Paterson University is deeply concerned with safeguarding the rights and welfare of all human subjects who participate in research projects conducted under its aegis. This concern extends to the intent of investigators to protect participants as well as to comply with the specific requirements established by the sponsors of its research.

These Guidelines provide the investigator with the information necessary to comply with University policy for review and approval of projects involving human subjects. In addition, it is hoped that they will confirm an awareness of the ethical and legal obligations assumed when such projects are undertaken. The investigator should also know the requirements of the Department of Health and Human Services as set forth in the Code of Federal Regulations 45 CFR 46 and certain other related laws and regulations on the protection of human subjects; and should be aware of and observe the standards established by the Declaration of Helsinki Recommendations Guiding Doctors in the Belmont Report, The Nuremburg Code, and Clinical Research.

In compliance with NIH guidelines, the inclusion of women and minority groups and subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection and/or exclusion of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants. For further information, refer to the NIH policy published in *NIH Guide for Grants and Contracts, 23*(11), 2-10. These documents are available for review in the Office of the Assistant Vice President for Graduate Studies and Research.

These Guidelines have been prepared by and for William Paterson University's Institutional Review Board (IRB). The IRB has developed a checklist which will be used by the Committee members for reviewing all research protocols submitted to them (see next page). Please review this list when preparing your protocol to make sure the appropriate documentation has been included in your submission. We hope that by providing this outline, the required information is present, the selection of subjects is equitable, the necessary signatures have been obtained, and the number protocols

tabled for inadequate information and/or approval can be reduced.

PLEASE NOTE: It is essential that proposals for *all research involving human beings* conducted by faculty and administrators be submitted to the IRB Chairperson. This includes research that may be eligible for exempted review and expedited review, as well as full review.

If a research study is to be conducted at more than one institution, researchers must submit the protocol to the IRB at each institution and forward one copy of the IRB approval letter from the cooperating facility. Researchers should be aware that non-competing continuation applications to Public Health Service (PHS) no longer are afforded a 60-day grace period for submitting PHS Form HHS 596 (certification of approval) to the sponsor. These proposals must have a current status (within a year of the funding start date) prior to processing through the Office of the Associate Vice President and Dean for Graduate Studies and Research. All correspondence and inquiries related to research involving human subjects may be directed to the IRB Chairperson.

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Part I. Regulatory Authority and Requirements

A. Regulatory Authority

This policy has been developed to assist the University in fulfilling its responsibilities as defined in several Federal regulations, primarily ***Title 45 Code of Federal Regulations, Part 46*** (a.k.a.: 45 CFR Part 46 and The Common Rule regulating the Department of Health and Human Services and 17 other Federal Agencies and Departments). It is also responsive to *Title 21 Code of Federal Regulation, Part 50* (21 CFR Part 50 for the Food and Drug Administration). These regulations, and this policy, all subscribe to the ethical foundation for human subject research as defined by ***The Belmont Report*** which was published by the the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979).

The Common Rule creates a system that provides for local control with federal oversight. The cognizant Federal Agency overseeing human subject research conducted by or at William Paterson University is the Office for Human Research Protections (OHRP), Department of Health and Human Services. (This was formerly known as the Office for Protection from Research Risks (OPRR) in the National Institutes of Health.)

The Responsible Institutional Official for William Paterson University is the Associate Vice President and Dean for Graduate Studies and Research. The Responsible Institutional Official is assisted in the oversight of human subject research by the Institutional Review Board for Human Subject Research at William Paterson University (IRB) and the IRB Administrator. The policy was developed by the IRB, reviewed by the Faculty Senate Research Council and approved by the Faculty Senate, and adopted as official university policy by the Provost and Executive Vice President.

B. Synchronization With Other University Policies

This policy does not conflict with or override other University policies that address related issues, and the requirements of those policies may be applicable to research projects at the same time as this policy. The policies include, but are not limited to, the *Academic Misconduct and Fraud Policy* (Adopted 1997), the *University Conflict of Interest Policy* (Adopted 2004), and the *University Financial Conflict of Interest and Commitment Policy* (Adopted 2004).

1. This policy assumes that the terms and requirements of these other policies are respected and fulfilled, and as appropriate, the IRB Committee may request information and/or certification that the individuals involved in research projects involving human subjects are in compliance with those policies.

2. The IRB will not approve a protocol and will rescind approval of any research that is not in compliance with other WPUNJ policies.

C. Studies Requiring Review

To assure the protection of living human subjects and to comply with federal law, William Paterson University requires that, prior to initiation, all research projects conducted by faculty and staff involving living humans as subjects or human material be reviewed and approved by the Institutional Review Board (IRB). This policy applies to all behavioral and biomedical research involving living human subjects or human material conducted by faculty, staff and students of the University regardless of the source of funding or the location of the study unless otherwise excluded by other sections of this policy. This policy also applies to all behavioral and biomedical research involving living human subjects or human material conducted at William Paterson University by any person or entity that is not affiliated with the University. Hereafter, all references to human subjects will represent both living human subjects and human material unless otherwise specified.

If the study is part of an application to a sponsoring agency, the human subjects protocol must be submitted for Committee review before or when the application is processed in the Office of Sponsored Programs. The application may not be submitted prior to the IRB′s review and approval of the research.

D. Studies That Do Not Require Review

1. Research conducted by the administration of the University involving its faculty, staff, students, alumni or other related constituency and concerning the operation of the University, its interaction with its various constituencies, or for other administrative purposes does not require review. For example, all research by the Office of Institutional Research and Assessment is exempt. However, research that will specifically identify respondents may require review and other conditions may require review as well. In all cases, the principles of informed consent should be incorporated as appropriate.

2. Research evaluating the conduct or outcome of a project, program, course or other activity sponsored by the University does not need to be submitted for review. This includes projects or programs that are grant funded. For example, a questionnaire at the end of a grant-funded seminar on the content of the program is exempt. Funded projects that include human subject research as a major component will require IRB review.

3. The pedagogical assessment or evaluation of the effectiveness or efficacy of curriculum materials, resources and educational techniques by faculty, staff and WPU students when that research does not offer substantially different learning outcomes does not require review. This includes situations where the students might otherwise be considered a vulnerable population requiring specific safeguards. Examples of activities not covered by this policy include: The comparison of one teaching technique against another technique when the alternative enables students to potentially learn as much or more as the original technique. The review of analysis of completed and graded assignments or coursework, especially following the term in which the materials were generated. Examples of activities that are covered and should be submitted to the IRB for review include situations when the evaluation or assessment includes interviews or discussions with students and/or their parents, the collection of data that would not normally be collected, the reporting of the research in a publication, the identification of students, the long-term tracking of students, and other similar situations.

4. Oral history interviews conducted to create a historical record. This does not include medical, psychological, sociological or behavioral background/demographic information of subjects.

All other research, especially research that the Investigator feels is within the definition of "Exempt" research, must be submitted to the IRB for determination of the review category.

Questions concerning whether a particular research project should be submitted for review should be directed to either the IRB Chair, the IRB Administrator, or another member of the IRB Committee.

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Part II. The Committee

The Responsible Institutional Official for William Paterson University is the Associate Vice President and Dean for Graduate Studies and Research. The Responsible Institutional Official is assisted in the oversight of human subject research by the Institutional Review Board for Human Subject Research at William Paterson University (IRB). The IRB is assisted by the IRB Administrator.

A. Responsibilities

1. The Committee is established as an Institutional Review Board (IRB) under the National Research Act of 1974, Title 45 Part 46 Code of Federal Regulation to review research involving human subjects conducted at or sponsored by the University. The review of research protocols is necessary to insure that: (1) Risks to subjects are minimized, and are reasonable in relation to potential benefits of the investigation. (2) Selection of subjects is equitable. (3) Informed consent is obtained by adequate and appropriate means. (4) Ongoing research is reviewed at least every 12 months unless the Committee requests a more frequent review.

2. The IRB determines whether a protocol will receive an Exempted, Expedited or Full Committee review. (See Section III.A.)

3. The IRB's role is not to comment on the research design of a proposal. The Committee does, in certain regulated areas, attempt to evaluate the scientific merit of protocols it reviews and offer constructive suggestions, where appropriate.

4. All records, minutes, protocols and other materials are maintained by the IRB Administrator.

B. Composition, Offices and Terms of Office:

1. The responsibility for the administration of this institution's policies insuring the rights and welfare of human subjects in research and investigation in all schools and departments rests with the Associate Vice President and Dean for Graduate Studies and Research. The Associate Vice President is assisted by the IRB whose members are appointed for the purpose of reviewing programs of investigation and research involving human subjects.

2. Composition: The Committee consists of: (1) Representatives of each of the University's Colleges as follows: Arts & Communication, 1 representative; Business, 1 representative; Education, 1 representative; Humanities & Social Sciences, 2 representatives; and Science & Health, 2 representatives. (2) Outside Members: 2 individuals who have no other affiliations with the University and who share one vote between them (if both are present at an IRB meeting, the senior outside member by length of service votes while the junior member has no vote). (3) The Vice President and Dean for Graduate Studies and Research and the Director, Office of Sponsored Programs. Consultants, advisors and other non-voting individuals may be appointed to the Committee as deemed necessary by the Committee and/or the University.

3. Offices: The Responsible Institutional Official is the Associate Vice President and Dean for Graduate Studies and Research. The IRB Administrator is the Director, Office of Sponsored Programs. The IRB Chair is the elected chairperson of the IRB Committee. Questions concerning human subjects and the activities of the Committee should be directed to the IRB Chairperson or the IRB Administrator. Principal Investigators are encouraged to consult the IRB Chairperson or the IRB Administrator to assure adherence to University Policy and Federal Regulations. Copies of all appropriate Federal Regulations are on file in the Office of Sponsored Programs.

4. Terms of Office and Appointment/Election: Each member of the committee may serve up to two three year terms (6 years total) and is appointed by the Provost & Executive Vice President on the recommendation of the IRB Committee and the Associate Vice President. The Committee Chair may serve up to three one year terms (3 years total) and is elected by the IRB Committee. The Vice President and Dean for Graduate Studies and Research and the Director of the Office of Sponsored Programs serve as ex officio.

C. Meetings

The IRB has two (2) regularly scheduled meetings each semester at which a quorum will consist of a majority of the current members of the IRB. Additional meetings may be convened by the IRB Chairperson as necessary. Minutes of the Committee meetings are recorded, and filed in the Office of Sponsored Programs.

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Part III. Review Categories and Processes

A. Initial Review

1. Studies Eligible for Exempted Review

The following categories of research are exempt from full Committee review. Research activities that (1) present no risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the exempted review procedure authorized by 45 CFR 46.101. Studies involving vulnerable populations may be ineligible for exempted review.

a. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; and (iii) information obtained has an impact on the subject's grade in an academic course or the subject perceives that the information may have an impact on his/her grade.

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (A)(1) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

c. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

d. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

e. The following three areas are exempt from Committee review and are not required to be submitted to the IRB. No information should be provided to the IRB for research falling under these categories. A complete and organized record of the research must be maintained by the researcher for a period of three years.

(i) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education

instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The use of educational tests within this context as a regular part of the educational strategy, technique, curricula, etc. does not effect the exemption of this type of research from IRB review. However, if information obtained will have an impact on the subject's grade or the subject perceives that the information may have an impact on his/her grade, a protocol must be submitted to the Committee for review under paragraph (A)(1) of this section and other sections as appropriate.

(ii) Research and demonstration projects which are conducted by or subject to the approval of William Paterson University administrators (Directors up through the President), and which are designed to study, evaluate, or otherwise examine its (a) educational, public benefit or service programs; (b) procedures for obtaining benefits or services under those programs or through the University; (c) possible changes in or alternatives to those programs or procedures; (d) possible changes in methods or levels of payment or reimbursement for benefits or services under those programs, or (e) for other appropriate reasons to improve the educational services provided by the University.

[Source: 45 CFR 46.101 with amendments and alterations]

(iii) Oral history projects.

2. Studies Eligible for Expedited Review

Approval of research that falls into the categories below may receive an expedited review process by the IRB.

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Please be advised that studies involving vulnerable populations may be ineligible for exempted review.

The categories of research that are eligible for Expedited Review include:

a. Clinical studies of drugs and medical devices only when condition (i) or (ii) is met:

(i) Research on drugs for which an investigational new drug application is not required. (Note: See regulations governing the Food and Drug Administration, 21 CFR Part 312.) (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(ii) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. (Note: See regulations governing the Food and Drug Administration, 21 CFR Part 812)

b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(i) From healthy, nonpregnant adults who weigh at least 110 pounds, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.

(ii) From other adults and children, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means as follows:

(i) hair and nail clippings in a nondisfiguring manner;

(ii) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(iii) permanent teeth if routine patient care indicates a need for extraction;

(iv) excreta and external secretions (including sweat);

(v) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(vi) placenta removed at delivery;

(vii) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(viii) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(ix) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(x) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are

not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (i) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (ii) weighing or testing sensory acuity; (iii) magnetic resonance imaging; (iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (v) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for nonresearch purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

[Source: 45 CFR 46.101(b) with amendments and alterations.]

3. Full Committee Review

Studies that are not included in either Sections 1 or 2 of this Part require Full Committee Review.

4. WPU Student Studies Eligible for Review

Very little human subject research by undergraduate or graduate students at William Paterson University should go beyond normal classroom or course assignments to require formal institutional review. Course faculty determine if their students' research should be presented to the IRB for review based on the conditions described below. The IRB strongly encourages faculty not to submit all student protocols to the IRB for review and to limit submissions to only those that fit the following conditions.

a. If any of the following conditions apply, the research must be submitted to the IRB.

(i) The study involves a vulnerable population.

(ii) The study collects sensitive personal information and/or requests the subject to undertake an activity that may elicit a significant negative psychological or physical response that is significantly different from the information or activities that are usually proposed by students in that particular course.

(iii) The research plan involves activities that are more extensive than or significantly different from the research plans that are usually proposed by students in that particular course.

(iv) The study includes potential physical or psychological risks for the researcher or the subject.

(v) The study collects personal, identifying information on the subject.

(vi) The research plan requires one-on-one interviews.

b. Student research that falls under the conditions of Part I (D) does not need to be submitted to the IRB for review even if it involves children.

B. Continuing Review

1. Studies That Require Continuing Review

a. Faculty, Staff and Outside Researchers: All research studies involving human subjects must be reviewed at least every 12 months as long as the project is continued. Dependent on the risk factors associated with some protocols, it may be necessary to have more frequent reviews.

b. WPU Students: This policy assumes that student research will be completed either during the academic semester in which it was approved or within two semesters following approval. This represents a period of less than 12 months. Therefore, unless other circumstances are identified during the initial review or afterward by the student and/or instructor, students are not required to submit their research for Continuing Review.

2. Protocol Changes:

a. If the investigator plans to make substantive changes in the research protocol, the requested change must be communicated promptly in writing to the IRB Chairperson. The researcher submits Appendix B, with a complete description of all changes to be made. If the proposed changes necessitate a change in the consent form or the testing instrument, then the revised consent form or testing instrument should also be attached.

b. Substantive changes include, but are not limited to: (1) a change in principal investigator or other senior project staff; (2) altering the subject pool, research location or research timetable; (3) altering the research plan, subject contact plan, or other activities involved in the research; (4) adding or deleting questions to the testing instrument(s); and (5) adding or deleting information to the Informed Consent Statement.

c. Changes that are not substantive include but are not limited to: (1) editorial or formatting corrections or improvements to Informed Consent Statements or testing instruments that do not change the content of the information/questions approved by the IRB; (2) minor increases or decreases in the number of subjects; (3) changes to the data analysis plan, and (4) changes in project support staff.

3. Adverse Reactions or Other Complications

If any unexpected adverse reaction or complication develops in the course of research on human subjects, the investigator must immediately notify the IRB Chairperson, the IRB Administrator or the Associate Vice President and Dean for Graduate Studies and Research by phone, email or in-person to provide information on the event and to initiate a University response if needed. A completed Appendix B form with a formal written report must be received by the IRB within 10 working days of the event, or sooner if requested. The IRB may suspend its approval of the research thus suspending the research project itself until a formal review is undertaken. Ultimately, the IRB may withdraw is approval thus ending the research project or reinstate its approval with or without conditions. The IRB and/or the University may be required to report adverse reactions and its findings to related funding agencies or other agencies.

4. Termination:

Investigators must notify the IRB Chairperson when a project is terminated. The researcher submits Appendix B and a brief report on the progress of the research. This report may be one provided to another WPU office, a WPU funding program, or to an external funder or supporter of the research. While the completion or termination of a project is not approved by the Committee, the report will be reviewed to insure that the research plan was followed and that there were no adverse reactions or complications that were not reported to the Committee.

C. Protocol Preparation Guidelines

1. Protocol Content Requirements

a. Initial Reviews:

(i) Faculty, Staff and Outside Investigators submit (a) Appendix A: Face Sheet completed in full, including required signatures, (b) the protocol narrative, (c) Informed Consent Statement, (d) testing instruments and (e) other materials/information as needed. Submit one original. Only hard copy originals are acceptable, electronic copies are not accepted because originals must bear signatures.

(ii) Undergraduate, graduate and outside investigators who are undergraduate students submit (a) Appendix C: Student Protocol Review Request completed in full, including required signatures, (b) Informed Consent Statement, (c) testing instruments and (d) other materials/information as needed. Submit one original. Only hard copy originals are acceptable, electronic copies are not accepted because originals must bear signatures.

b. Continuing Reviews: Everyone submits (i) Appendix B: Continuing Review completed in full, including protocol number and required signature, (b) report on status of research, and (c) other materials/information as needed. Submit one original. Only hard copy originals are acceptable, electronic copies are not accepted because originals must bear signatures.

2. Protocol Narrative Preparation for Faculty, Staff and Outside Researchers

The protocol narrative must be a summary of the research plan outlined according to factors which the Committee considers essential for its review. The protocol narrative should be prepared according to the following outline.

a. Purpose: Summarize the purpose of the study, the hypotheses or the guiding questions, and a statistical analysis section.

b. Duration: Provide an estimate of the duration of the entire study. Please note that Committee approval is required every 12 months while the study continues or at such intervals as designated by the Committee after final review.

c. Subject recruitment and selection: Provide the numbers of subjects to be invited to participate and, if it is an experiment, specify those to be included as control subjects. If subjects are excluded because of age, gender, economic status, or race, the reasons for the exclusion must be documented. Describe any inducements which will be offered to subjects, e.g., cash payments, gifts, credit vouchers, free hospitalization, medication, clinical testing, or the like. Summarize the process of obtaining potential subjects. All advertisements to recruit research subjects must be submitted for approval. For studies using patient populations, attending or referring physicians must have a reasonable opportunity to affect the manner in which their patients are invited to participate. If the patient has not previously given consent to the disclosure of his/her name for research, the patient first should be contacted by his/her physician with the investigators request. Include in the application copies of all letters to subjects and intermediaries. Indicate all special categories of subjects to be included, e.g., mentally retarded or disabled, minors, pregnant women, prisoners, etc. Please note that administrative or researcher convenience is generally not a justification for use of special groups with limited capacity to give consent if alternative groups are available.

d. Location: Provide the specific name of the school, business, clinic, hospital or other agency from which subjects will be recruited and where the research will take place. For locations other than University facilities, documentation must be submitted that supervisory personnel of both the agency and the University are aware of the project. The researcher is responsible for fulfilling the IRB requirements at all non-WPUNJ facilities and to provide proof of IRB review and approval if it is required by that facility.

e. Background: Describe succinctly and clearly the past findings which led to the plan for this project. A summary of the relevant literature in the area of interest and reports of previous studies can be included. Explain the need for all the various methodologies employed by this protocol (lack of alternative, relative risk of alternative, etc.).

f. Research design: Prepare an orderly scientific description of the intended procedures as they directly affect the subject. Include the number and estimated length of time, length of time for various procedures (e.g., interviews, completing questionnaires, etc.) and frequency of repetition; randomization; any manipulation which may cause discomfort or inconvenience; doses and routes of administration of drugs; amount of blood to be withdrawn; plans for follow-up hospitalizations; etc.

If there is a point at which the study procedures may be discontinued, state how this point will be determined. Include measures which will be taken to treat side effects or to handle or refer problems identified during the study. Include one (1) copy of questionnaires or rating scales to be used.

If drugs or devices are administered or used, the following questions must be answered. Does the drug or device have FDA approval? What is the name of the drug or device company? If the drug or device is investigational, does it have an Investigational New Drug (IND) or Investigational Device Exemption (IDE)? What is the IND or IDE Number? If the drug or device is marketed, is it approved at the dose level you plan, for this purpose, or by this means of administration or use?

Clinical drug and medical device trials should have a copy of an indemnification clause attached to them with the appropriate signatures. A Sample Indemnification form is included as Appendix E. These indemnification documents must be between the Trustees of the William Paterson University and the Sponsor. All indemnification agreements must be signed by the Associate Vice President and Dean for Graduate Studies and Research. An IND or IDE number must be submitted for all investigational drugs and devices as well as an investigator brochure with background information and experience to date on the specific test article.

g. Potential risks: Describe and assess any potential risks (physical, psychological, social, economic, monetary, legal or other) and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used. "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests. All proposals should include a risk/benefit statement.

h. Consent procedures: Describe consent procedures to be followed, including how, when, where, and by whom informed consent will be obtained.

i. Protection of subjects: Describe procedures (including confidentiality safeguards) for protecting against or minimizing potential risks, and assessment of their likely effectiveness.

j. Potential benefits: Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work.

k. Risk/Benefit statement: Analyze the ratio of the benefit and risk to be obtained from the study relative to the risks involved.

3. Protocol Narrative Preparation for Undergraduate and Graduate Students

Undergraduate and graduate students complete Appendix C: Student Research Protocol Review Request by providing responses to a series of questions that will define the proposed research in a consistent manner for the IRB. The form must be signed by both the student and the faculty sponsor. In the case of a group project, each student may sign the form but it must be signed by the lead student of the team. These questions are:

a. What is the intent or goal of the study? What is your hypothesis?

b. Research Design: What is the research design of the study? How will it be conducted? What information will be collected? How will it be collected? How will it be analyzed?

c. Your Human Subjects: Who will be you subjects? How will you select or contact them? Are your subjects children or minors, prisoners, or vulnerable for some other reason? Explain how the rights, identify and confidentiality of your subjects will be protected. If the study will be off campus, where will it be done and have you obtained permission to use this/these location/s?

d. Outcomes: What is the anticipated outcome of this research? How will you use the results of this research?

e. Benefits: What are the benefits of this research? Are there any direct benefits to the subjects? How will this information add to the general body of knowledge for your area of study?

f. Risks: What are they physical or emotional risks to your subjects? How do you plan to minimize these risks? What are the physical or emotional risks to the researchers involved in this study? How do you plan to minimize these risks?

g. What are the anticipated start and completion dates of your study?

4. Informed Consent Statement

The Informed Consent Statement should be a succinct statement which gives reasonable information about the study, its procedures, benefits, risks, duration and alternate therapy to enable the subject to make a meaningful decision about participation. The University recognizes two types of informed consent: passive and active.

a. Passive Informed Consent Statements: Passive Informed Consent Statements may only be used for anonymous surveys and questionnaires and must be printed at the beginning of the survey or questionnaire. A subject may be given a second copy of the survey or questionnaire if they request it so that they may have a copy of the informed consent statement. Alternative methods will be considered.

(i) Heading: The heading of the survey or questionnaire must (1) identify William Paterson University, (2) the title of the study, (3) identify the name(s) and telephone number(s) of the responsible faculty or outside investigator(s) or just the name of a student investigator, (4) identify the course name and the name and telephone number of the faculty sponsor for student research, and (5) the date. The study title should be carried at the top of each subsequent page.

(ii) Body: The body of the informed consent statement will include: (1) the purpose of the study, (2) a description of the subject pool and selection procedure, (3) the risks/benefits to the subject, (4) the use and confidentiality of the information collected, (5) that participation is voluntary, (6) a subject rights and withdrawal statement, and (7) additional contact information

(if needed).

A sample Passive Informed Consent Statement is included as Appendix D.1.

b. Active Informed Consent Statements: Active Informed Consent Statements should be used for all purposes except anonymous surveys and questionnaires. It should be a separate document from the testing instrument. It should describe the research, what is expected of the subject, and the subjects rights concerning his/her participation. It should include a place to sign and date the statement.

(i) Heading: It should be entitled Informed Consent Statement and sub-titled with the name of the study, and must (1) identify William Paterson University, (2) the title of the study, (3) identify the name(s) and telephone number(s) of the responsible faculty or outside investigator(s) or just the name of a student investigator, (4) identify the course name and the name and telephone number of the faculty sponsor for student research, and (5) the date. The study title should be carried over to the top of each subsequent page.

(ii) Body: The consent statement should be written in clear, understandable English or the language of the subject population. It must explain the purpose of the study and precisely what will be done to or with the subject. It must provide adequate information for the subject to decide whether or not to participate. It may not include language by which the subject is made to waive, or appear to waive, any of his/her legal rights or to release the institution or its agents from liability for negligence. It is recommended that all consent forms be written in the same person throughout (i.e.: "I understand that..."), and that scientific terminology be defined for a lay person's understanding. Documents must also be thoroughly edited for spelling and typographical errors. The following points must be covered in the consent form:

(a) Purpose: The general purpose of the study should be expressed in lay terms and should clearly state the nature of the research project. The subject should be told that he/she is being asked to participate in a research study.

(b) Selection of Subjects: The subject must be informed of the reason why he/she has been invited to participate in this study.

(c) Procedures: The subject must be informed exactly what his/her participation will involve. This may include randomization, questionnaires, video-taping, diets, withholding of standard treatment, follow-up studies, the length and frequency of hospitalization, types of medication, placebo administration, types and numbers of tests, amount of blood to be withdrawn (in terms a lay person can understand such as ounces, tablespoons, teaspoons). If a test article is involved, the consent form should explain that: (1) it is routinely used for the proposed purposes of the study, or (2) it is experimental and not approved for general use in the United States but has been approved for use in this study. Other details may be included as well.

(d) Risks: It must be clearly stated if participation in this study may bear some known or unforeseeable hazards, discomforts, or inconveniences. These may include side effects of drugs, procedural hazards, withholding of therapeutic regimen of proved value, time

involved, or an emotional or psychological response. The disclosure of risks must also include the implications of randomization of subjects and of placebo administration. If double-blind studies are involved, it should be made clear to the subjects that neither the investigator nor the subject will know which treatments the subject is receiving during the study. Special implications of crossover studies should be explained (e.g., the subject who has a beneficial response to the experimental drug may have to do without it for the placebo phase). For any double-blind drug study, the subject must be informed that the code will be broken in the event of an emergency. (Note: Special consent forms are required for special protocols involving radioactivity.)

(e) Benefits: The benefits to the subject, if any, are to be explained. If there are no benefits for subjects, this too should be clearly stated.

(f) Payment: Subjects should be told specifically what charges if any, they are responsible for and which will be paid for by the sponsor. If subjects are to be paid for participation, the schedule of payment and the dollar amount must be documented with specificity.

(g) Alternatives: In therapeutic studies, alternatives should be described. The description would include other accepted treatment regimens, as well as a brief description of the benefits and risks of each alternative.

(h) Confidentiality: Subject must be informed of the steps that will be taken to assure confidentiality, particularly when personally identifiable information is to be recorded. Coding of data, maintaining separate files for identifying information and limiting access to investigators only, as well as eventual disposal of recordings are means of assuring confidentiality and should be described. In some cases, instructions concerning who may be contacted for answers to pertinent questions and/or who will receive information derived from the study should be addressed. Research subjects involved in clinical trials must be told in the consent form that representatives of the drug/device company and the FDA may review the data collected for the study and that the information will be kept confidential except as may be required by law. In studies receiving Federal funding support, research subjects must be told that personal information will be kept confidential except as may be required by law.

(i) Withdrawal: The subject must be informed that he/she is free to decide whether or not to participate and is free to withdraw from the study at any time. The subject should be assured that non-participation or withdrawal from the project will not affect the standard care in a health care setting, or the evaluation of performance or grades in an educational setting, or other services he/she will receive in other settings as appropriate. There must also be assurance that a decision not to participate will not prejudice future interactions with the faculty member, investigator, or institution particularly if any potentially coercive relationship exists between the investigator and subject, such as physician-patient, employer-employee, faculty-student, etc.

(j) Injury/Complications: Prospective subjects should be advised as to the availability or nonavailability of medical or psychological treatment or compensation for injury incurred as a result of participating in biomedical or behavioral research. For research involving

more than minimal risk, an explanation as to whether any compensation and/or medical treatment and/or counseling is available if injury occurs and, if so, what they consist of, or where further information may be obtained. The Committee has approved statements which must appear in all consent forms, according to the following criteria:

(1) Studies where no threat of injury exists, no additional statement is necessary.

(2) The usual human study involving healthy volunteers or patients in whom complications of the research are expected to be identifiable, the consent form should state: *"I understand that in the event of injury resulting from the research procedures, medical treatment in excess of that covered by third party payors will be provided without cost to me, but financial compensation is not available."* (NOTE: This statement is the one which should be included in most consent forms.)

(3) There are a number of disease processes in which complications are particularly severe, frequent, and/or various. e.g., some types of cancer, organ failure, or massive infection. For some categories of investigation in such patients, it may be unrealistic to provide assurances that distinguish complications of research and those of the natural history of the disease. In these special circumstances, it is suggested that the consent form contain a statement such as: *"I understand that complications may arise during the course of therapy either due to my disease or due to the treatment. I have been advised that therapy for any such complications will be carried out by my doctors and costs associated with such care may be provided by third party payors. I have been advised that no compensation will be provided to me as a result of my participation in this study."* This alternative statement should only be employed when the natural history of the disease and the likely complications of the research are not expected to be separately identifiable.

(k) Radiation Considerations: If the research involves the administration of ionizing radiation to subjects for other than clinical purposes, the consent form must describe in lay terms some assessment or description of the radiation effect and risks. Advice regarding documentation of this section can be obtained by contacting the IRB Chairperson.

(l) Subject Rights: The following statement regarding the rights of research subjects *must appear* in all consent forms: *"I understand that if I wish further information regarding my rights as a research subject, I may contact either the Associate Vice President and Dean for Graduate Studies and Research at William Paterson University by telephoning 973-720-3093 or the Institutional Review Board Administrator by telephoning 973-720-2852."* One or both of these names may be included.

(m) Conclusion and Signatures: The last statements in the consent document should read, *"I have read and received a copy of the consent form. I have discussed my participation and understand what will happen and what will be expected of me. I understand the my risks. I agree to participate in this research study."* With reference to the requirements above and to document the fact that informed consent has been obtained, the consent form must be signed by appropriate individuals. The subject must sign a statement that he/she agrees to participate in the project. If the subject is a minor, spaces should be provided for

both the minor and a relative/guardian, (indicating the relationship) to sign. In the case of subjects whose capacity or competence to give consent is limited for any reason, the signature of the required legally authorized representative must be obtained. Also, space should be provided on the form for the signature of the investigator/interviewer and for a witness if needed.

Sample Active Informed Consent Statements are included in Appendix D.2.

(iii) Ensuring subject understanding: The subject should be encouraged to ask questions in order to be fully informed of the proposed research study. The consent form should include a statement that the subject has been given the opportunity to ask questions and has had them answered to their satisfaction. If the proposed procedures are complex or hazardous, subjects should be encouraged to discuss them with other appropriate experts, family or friends, e.g., their own physician, mentor, teacher, spouse, etc., before making a decision. If the experiment involves a considerable degree of risk, the subject must be briefed twice with at least 2 days intervening between briefings. If it is anticipated that the second briefing may have to be waived in some circumstances, the investigator should include information to this effect in his/her protocol for approval by the Committee. If the subject is not a fluent speaker and reader of English an interpreter should be present at the time that the informed consent statement is discussed and a statement should be provided to the subject in his/her primary language. Prior to signing the consent form, the subject should be asked to reply, in his or her own words, and without immediate reference to the consent form, to the following questions: (Do not include these questions in the consent form)

(a) What is the purpose of this study?

(b) What will be done?

(c) What risks and discomforts may occur from participating in this study?

(d) What benefits may accrue to subjects from participating in this study?

A person may participate in an experiment only if his/her answers demonstrate an informed and educated understanding of the experiment.

(iv) Copies: Each subject, each advocate, legally authorized representative, and each witness who signs consent for a minor subject must receive a copy of the signed document. The principal investigator must retain in his/her confidential files copies of consent forms signed by each subject in the study. The consent forms may not be kept with the data and any keys linking the consent statements and data must be kept in a third separate location.

D. Approval Processes and Actions

1. Review Prior to Submission to the Committee:

a. Appendix A: Face Sheet: After preparation of the protocol and prior to its submission to the Committee, the investigator must submit the complete protocol to his/her department

chairperson for signature to indicate awareness of the submission and departmental support for the research. For projects involving personnel from more than one department, investigators must submit the protocol to the chairperson of each department. If the any of the researchers are the department chairperson, then their Dean/Vice President will sign the protocol to indicate awareness of the submission and both departmental and college/unit support for the research.

b. Appendix C: Student Research Protocol Review Request: After preparation of the protocol and prior to its submission to the Committee, students must submit the protocol to an appropriate faculty sponsor for signature. This will indicate that the faculty sponsor has reviewed the research, supports the project, and accepts responsibility for the actions of the student in undertaking the project.

2. Protocol Review Procedures:

a. Initial Protocol Reviews

1. Faculty, staff and outside investigators submitting a protocol for initial review will use Appendix A: Protocol Face Sheet. WPU undergraduate and graduate investigators, and outside investigators who are undergraduate students, submitting a protocol for initial review will use Appendix C: Student Protocol Review Request.

2. Protocols will be sent to the IRB Administrator who will coordinate the review and all actions concerning all protocols. All protocols are first reviewed by either a member of the IRB Committee (for protocols with Appendix A) or the IRB Administrator (for protocols with Appendix C). If the proposal qualifies for an Exempted or Expedited Review, it is reviewed by that same person, the investigator is notified of the reviewer's decision and the protocol is sent to the Committee for affirmation. If the proposal qualifies for a Full Committee review, it is reviewed by the Committee at the next regular meeting (or a special meeting is scheduled for the review) and then the investigator is notified of the Committee's action. The investigator(s) may begin his/her/their research after notification from the IRB Administrator on behalf of the Committee.

3. Faculty and staff protocols are reviewed within 3 weeks of submission. Student protocols are reviewed within 3 to 5 working days of submission. These review periods are contingent on the need to request or gather information related to the review. Every effort will be made to review protocols in a timely manner, but no guarantees can be made as to when a particular protocol will be reviewed and they are assigned on a first-come-first-served basis. Investigators are urged to submit their studies as far in advance of a beginning date of their research as possible in order to insure timely review, especially when the submission of an application for funding is contingent on IRB approval. While the Committee wishes to be helpful to all investigators, it cannot make exceptions for last minute requests.

b. Continuing Reviews

All faculty and staff investigators submit Appendix B: Continuing Review Face Sheet for continuing review, adverse reaction, or termination reviews. The Continuing Review Face Sheet and attached materials are reviewed by the IRB Administrator and are then sent to the Committee for review and approval. The investigator(s) may continue his/her/their research pending notification by the IRB unless an adverse reaction or other complication is involved.

3. Action by the Committee:

a. Committee Review of Exempted and Expedited Protocols

The investigator will be notified after the initial reviewer makes his/her determination and, if approved, may begin their research. All approved exempted and expedited protocols are reviewed by the full Committee at its next meeting. The Committee may affirm or change the reviewer's determination. The investigator will not be notified if the Committee affirms the initial determination. The investigator will be contacted by the IRB Chair and/or Administrator if the Committee does not affirm the initial determination to discuss the decision, the issues involved, if the research is to be temporarily suspended or terminated, what is required to obtain the approval of the Committee, and a date for fulfilling any requirements or answering any questions or concerns.

b. Full Committee Review Process

(i) After a protocol has been identified for full Committee review it is placed on the agenda of the next regular committee meeting, the investigator is notified that the protocol will receive a full Committee review and when the meeting will take place. If the next regular meeting has not been scheduled, a meeting will be scheduled.

(ii) A list of all protocols for full Committee review is sent to each Committee member. A copy of each protocol is sent to the IRB Chairperson and at least one additional Committee member who, with the IRB Chairperson, are assigned as primary reviewers. The primary reviewers are responsible for recommending the IRB to: 1) approve the protocol as submitted; 2) approve the protocol contingent on specific revisions; 3) table the protocol for substantive change and resubmission to the Committee, or 4) disapprove the protocol. (Note: Descriptions of these choices follow.) At the Committee meeting, each protocol is discussed by the entire Committee. The Committee may ask the investigator or other individuals to attend the meeting to discuss the research and/or provide information to the Committee on the area of research, research methodology or other issues related to the protocol. The Committee then determines if it will accept or not accept the recommendation of the primary reviewers. If the primary reviewers' recommendations are not accepted, the Committee may determine the disposition of the protocol according to the above (1, 2, 3, or 4). The IRB Chairperson will notify the investigator in writing of the action as soon as possible after the determination is made. Activities related to each action will proceed as follows:

(1) Approval as submitted: The investigator will be sent an approval notice including a statement of his/her responsibility to report adverse reactions and request Committee review of modifications or revisions to the protocol. The investigator will also be

informed of his/her responsibility to submit a summary of the project every twelve months for continuing review or more often if requested by the Committee.

(2) Approval contingent upon specific revisions: The investigator will be sent a notice describing the revisions requested with specific reply-by date. After revising the protocol and/or consent form and/or testing instrument, the investigator will return one copy with the revisions underlined or highlighted to the IRB Chairperson. If the revisions are deemed satisfactory by the primary reviewers, an approval notice will be sent to the investigator. If the investigator disagrees with requested revisions, he/she may present in writing the reasons to the IRB Chairperson. The Chairperson will review this response and if necessary request the investigator to appear at the next Committee meeting to answer questions and discuss relevant matters. The investigator will be notified in writing of the Committee's final decision.

(3) Tabled for substantive change: The investigator will be sent a notice describing the reason for tabling IRB decisions and outlining revisions or clarifications necessary for reconsideration with a specific reply-by date. The primary reviewers will discuss the Committee's concerns and requests with the investigator and the investigator may request to appear at the next Committee meeting to discuss the protocol, the Committee's decision and relevant matters. The investigator will submit his/her response to the IRB Chairperson for distribution to and review by the Committee.

(4) Disapproval: The investigator will be sent a notice describing the reasons for disapproving the protocol. Disapproval of the protocol usually occurs when the Committee determines that the risk of the procedures outweighs any benefit to be gained. The investigator may discuss the Committee's review with the Chairperson and/or submit a revised protocol for review at the next scheduled meeting. The investigator may request to appear at the next Committee meeting to discuss the protocol, the Committee's previous decision and relevant matters during the Committee's discussion of the revised protocol.

4. Institutional Endorsement:

Many agencies which fund research require certification by an authorized official of the institution that research involving human subjects as described in the application has been approved by an IRB. The University will provide the sponsor with appropriate documentation of the Committee's approval. The review of research that falls under either the Exempted or Expedited review categories should be completed prior to the preparation of documentation and submission of the proposal. For research that will require a full Committee review, a preliminary review and recommendation for approval by the IRB Chairperson and one additional IRB Committee member is required prior to institutional endorsement and submission of the proposal. Full Committee review and approval is required prior to beginning the research whether or not the research is funded.

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Part IV. Special Classes of Subjects and Special Considerations

A. Federally Stipulated Special Classes of Subjects

Federal regulations provide specific requirements for three classes of subjects. Any research involving these classes of subjects must be reviewed by the full committee unless the specific exemptions for each class are met. The primary reviewers and the Committee will refer to the appropriate subpart of 45 CFR Part 46 during its consideration of the protocol.

1. Fetuses and Pregnant Women (45 CFR Part 46, Subpart A). Exemptions for Fetuses: None. Exemptions for Pregnant Women: Exempted Review items as described in Part III.A.1e and Expedited Review items as described in Part III.A.2.e, f and g only if there are no biomedical elements to the research plan.

2. Children and Minors (45 CFR Part 46, Subpart B). Exemption for Children aged 0 to 13 Years: Exempted Review items as described in Part III.A.1e . Exemptions for Minors aged 14 to 15 Years: Exempted Review items as described in Section 13 (A) (1) and Expedited Review items as described in Part III.A.2.e, f and g if there are no biomedical elements to the research plan and the research does not collect sensitive personal information and/or request the subject to undertake an activity that may elicit a significant negative psychological or physical response. [Note: In New Jersey, individuals who have reached the age of 16 have reached the ″age of majority.″] All children and minors must assent to their participation in research along with their parent/guardian′s approval for their participation; children aged 7 to 15 years must also be involved in discussing the Informed Consent Statement and must sign the statement along with their parent/guardian to indicate their assent to participate.

3. Prisoners (45 CFR Part 46, Subpart B). Exemptions: None.

B. William Paterson University Stipulated Special Classes of Subjects

1. Individuals with Limited Ability to Voluntarily Participate in Research:

For the subjects who may perceive that their ability to participate freely and honestly is limited because of their specific personal circumstances and the subject of the research, the Committee will work with investigators to insure that all possible concerns are addressed prior to the approval of a protocol. Subjects in this group may be: (a) residents of a hospital, nursing home or other health care facility when the focus of the research is on the quality of their care, the type of procedures or tests they are receiving or have received, or the facility′s staff; (b) employees of a business when the focus of the research is on the workplace, the employer or other employees; (c) students in a course or class when the investigator is the instructor and the subject of the research is not related to the course or exempt as per Part III.A.1.e. In these cases, additional safeguards will be used to shield responses from all individuals except the investigator and other project staff, to separate informed consent statements from testing instruments, and by avoiding questions or opportunities which require subjects to specifically identify individuals or situations.

2. WPUNJ Students or Employees as Research Subjects:

a. For students and instances where WPUNJ faculty or staff use WPUNJ students in research studies, the following guidelines are intended to (1) protect students from unintended coercion

or unequal benefit from participating in research that involves face-to-face interviews or testing, observation in a controlled location, or a similar activity that is beyond the scope of an anonymous survey, and (2) encourage students to voluntarily participate in research activities with option of providing extra credit. These guidelines do not supersede any course requirements, are not intended to restrict any faculty member's freedom to make assignments or conduct their classes, offer extra credit, or infringe on any aspect of achieving the goals of individual courses unless these activities are in clear contradiction to the University's IRB Policy.

A WPU faculty person may include students who are currently in his/her classes in research he/she is undertaking within the following contexts:

(i) Controlled, out-of-classroom, laboratory-based research.

(a) The professor will offer equal credit to his/her students in his/her class who: (a) participate in a research study for not more than 3 hours during the semester; (b) completes a ungraded short paper or other appropriate academic activity related to research as determined by the professor; (c) attends a research colloquium; and (d) other options.

(b) The professor will recruit students in his/her classes as he/she would recruit other students or WPUNJ employees to be employees. These activities may include: (a) a publicly posted notice Volunteers register by calling the investigator, or (b) direct recruitment in his/her class, by other faculty in their classes, or individually as opportunities are presented. Volunteers may register on-the-spot or contact the faculty researcher directly later on. Recruitment posters or announcements will include information taken from the informed consent statement.

(c) The amount of optional credit toward a student's final grade point average for participating in one of the three research activities would be up to the discretion of the professor. The IRB suggests a rate of 1 credit/100 credits toward the student's final average for the class.

(d) Students would not be penalized beyond not receiving their extra credit for not showing up for a scheduled research appointment, for not completing a paper or for not attending a colloquium.

(ii) In-class or classroom-based research.

(a) When the identification of students is a required part of the study, students must be fully informed of the study and be provided with an appropriate method for not participating in the study, such as not completing but handing in a survey with a cover page masking answers. No course credits will be offered for participation and no penalties will be assessed for non-participation. Survey or other responses will remain sealed until the end of the semester.

(b) When the identification of students is not a required part of the study, students must be fully informed of the study and be provided with an appropriate method for not

participating in the study, such as not completing but handing in a survey with a cover page masking the unanswered survey. No course credits will be offered for participation and no penalties will be assessed for non-participation. A WPU faculty person may not include students who are currently in his/her classes if the research involves an issue that may affect the faculty's perception of that student (such as sensitive issues like sexual attitudes or behaviors, racial attitudes, mental health, the use of alcohol or illicit drugs, cheating, plagiarism, or illegal activity). Additional confidentiality safeguards may be required by the IRB based on the research plan and need to identify individual student's data.

b. For employees, the same concerns and process in paragraph 2 (a) of this section applies. The IRB encourages the use of employees in research undertaken at WPUNJ.

C. Other Special Considerations

1. Sensitivity of Questioning:

Subjects can be harmed psychologically in the course of a survey or interview study as well as in manipulative experimental situations. It requires sensitive anticipation to avoid these apparently innocuous intrusions. Subjects are often asked to reveal unpopular attitudes, such as resentments toward some social group, or possible demeaning social characteristics, such as low income or receipt of welfare payments. The subjects may be led into admissions or behaviors that in later reflection they find to be deviant, immoral, unjust, humiliating or overly embarrassing. Such research situations should be designed carefully, to provide a supportive context, and only carried forward if the threats to subjects' comfort are essential and severely minimized.

2. Medical Records and Chart Review:

Studies which involve only chart and record review sometimes pose significant risk to patients. The most common breach of confidentiality is exposure of possible embarrassing information without the knowledge or consent of the patient. Such studies may also lead to recruitment of patients into future non-therapeutic studies in a manner which may provoke the patient to ask how his/her record was revealed to someone not part of his/her therapeutic team. The present policy is to require review of studies involving chart review or data collection and analysis:

a. When the possibility of contacting patients or their physicians is contemplated.

b. If identifiable information will be collected or disclosed to anyone other than the investigators. An expedited review should be requested for studies in this category. (See Part III.A for studies eligible for expedited review).

3. Residual Body Fluids, Tissues and Recognizable Body Parts:

Studies which utilize residual bodily fluids, tissues and/or recognizable body parts from clinical laboratories, pathology laboratories, or other clinical or hospital settings which may or may not be personally identified or linked to a subject must be reviewed. Investigators conducting research of this nature should be familiar with the policies regarding recognizable human body parts and the

promulgated standard entitled, "Occupational Exposure to Blood-borne Pathogens." Information in this regard may be obtained by contacting the IRB Chairperson. Expedited review of such studies may be authorized if all of the following circumstances exist:

a. The fluid, tissue or body part is obtained in a procedure that is entirely predicated on clinical grounds or donated through the Gift Registry.

b. Consent has been obtained for the procedure.

c. Extra fluid or tissue is not removed, and the materials used for research is that remaining after clinical use.

4. Emergency Approval for Medical Care:

Nothing in these regulations is intended to limit the ability to provide emergency first aid or limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law. Questions concerning emergency approval should be directed to the IRB Chairperson.

5. Research Involving Administration and Use of Ionizing Radiation:

To comply with regulations of the U.S. Nuclear Regulatory Commission, any use of radiation or radioactive materials requires approval by the University. Information in this regard is available from the IRB Chairperson. In addition to submission for full Committee review, all protocols involving ionizing radiation for other than clinical management must be approved by a cooperating sponsoring institution with a nuclear license.

6. Research Involving Human Blood, Blood Products, Body Fluids or Tissue Specimens:

The Occupational Safety and Health Administration (OSHA) promulgated a standard entitled, "Occupational Exposure to Blood-borne Pathogens" that took effect March 6, 1992. The standard, which recognizes unique hazards to health care workers, applies to all laboratories and clinical settings that use human blood, blood products, tissue specimens or body fluids. It requires the employer to provide annual training in the proper handling of blood-borne pathogens. Training is available for University personnel. For more information or to obtain a copy of the University's Exposure Control Plan, please call the IRB Chairperson.

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Part V. Training Certification

1. Training Certification

1. To insure that investigators involved in human subject research and faculty teaching courses that include research on human subjects have an adequate background in the ethical principals and requirements governing research involving human subjects as well as the requirements and processes related to the conduct of human subject research at WPUNJ, these investigators and

faculty must provide certification of human subject research or research ethics training to the IRB. Certification must be received prior to the acceptance of a research protocol for review. Protocols from students of an instructor who has not been certified will not be accepted. (This is not applicable for students involved in a faculty research project as defined in Paragraph B of this section.)

Certification of the successful study of the ethical principals governing research involving human subjects and the requirements and processes related to the conduct of human subject research at WPUNJ will be provided by reputable organizations selected or approved by the IRB or the Associate Vice President and Dean for Graduate Studies and Research. The certification must represent a course a study covering all issues deemed essential by the IRB.

2. This requirement applies to:

a. Faculty, professional staff and others who are the principal investigator, co-investigators, senior-level project support, or other project support staff who have direct contact with subjects in any manner, with original data collection tools/resources, or with information that identifies subjects.

b. Faculty teaching courses that include instruction related to human subject research and/or requiring students to undertake human subject research that falls under the purview of this policy.

c. Graduate and undergraduate students who are undertaking human subject research for a course that does not normally include human subject research AND when the course faculty is not certified.

d. All members of the IRB, the Responsible Institutional Official, the IRB Chair, and the IRB Administrator.

e. Deans and Department Chairs of academic units that include faculty who are involved in human subject research and/or have courses and/or students that include or undertake human subject research.

f. Vice Presidents, Associate and Assistant Vice Presidents, and Directors of administrative units that include staff who are involved in human subject research.

g. Outside researchers who wish to undertake research on the WPUNJ campus or involving WPUNJ students, faculty, staff or visitors. (Certification obtained by at the home institutions of outside researchers may be submitted for review by the WPUNJ IRB; the WPUNJ IRB may accept an appropriate level of knowledge competency of the WPUNJ requirements and processes as demonstrated in the outside researcher's protocol.)

3. This requirement does not apply to: (a) Project staff who do not have contact with subjects, original data or identifying information. (b) Undergraduate and graduate students in a course taught by an instructor who has received certification. Certification for undergraduate and graduate students will be the certification of their instructor.

4. To assist investigators, project staff, instructors, students, administrators and others in the fulfillment of this requirement, a training certification program will be developed and maintained. The program will address both Federal and local concerns and requirements. The University will review and accept/reject certification from other institutions. The University will maintain a record of certifications.

5. A certification will remain effective throughout the research period of an approved protocol and for a period of three years following the completion of the investigator's last research project. A new certification will then be required prior to the approval of a new protocol for research involving human subjects. The three-year time period will insure that investigators are up-to-date with changes to regulations and processes.

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Appendices

APPENDIX A: PROTOCOL FACE SHEET

APPENDIX B: CONTINUING REVIEW FACE SHEET

APPENDIX C: STUDENT PROTOCOL REVIEW REQUEST

APPENDIX D: SAMPLE INFORMED CONSENT STATEMENTS

1. Passive Informed Consent Statement
2. Active Informed Consent Statements
    a. Interviews and other minimal risk studies
    b. Studies with more than minimal risk
    c. Consent for venipuncture and other simple invasive procedures

APPENDIX E: SAMPLE INDEMNIFICATION CLAUSE

APPENDIX F: Not Used

APPENDIX G: PROTOCOL REVIEW FORM

APPENDIX H: DEFINITIONS

Appendices A through G inserted following this page.

Appendix H Definitions

Provided by *The Common Rule*, the *IRB Guidebook* (OHRP, 2001), the previous editions of this policy (1996, 1999), or were created for this edition. The definitions are divided into five categories: Human Subject Research and Research Activities, Researchers and Officials, Research Subjects, Review Process and Considerations, and Policies.

1. Human Subject Research and Research Activities

Research: A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge [Common Rule, 46 CFR 45.102(d)].

Human Subject Research: In clinical or educational institutions, the boundary between research and experimental and innovative care and teaching is a complex and controversial issue. However, for the purposes of this policy, human research is any activity which has the intent of securing information from humans for the purpose of advancing generalizable knowledge. Such activity may or may not differ from customary professional or medical practice [Common Rule, 46 CFR 45.102(f)].

Classroom-based Research: Demonstrations, exercises, and/or experiments designed for the exclusive purpose of student education, e.g. teaching, interviewing by having students interview each other and derive "findings", with no intent to generate data whose main purpose is the advancement and dissemination of generalizable knowledge beyond the classroom setting is not considered a research activity. However, some research conducted by students for course assignments may constitute human subject research when it exceeds the bounds of the classroom and includes significant contact with subjects outside the confines of the classroom. [WPU-IRB Policy, 1996.]

Research Activities: The activities or procedures involved in research may be invasive or noninvasive and include placing subjects in various therapeutic or research situations; removal of body tissues or fluids; administration or application of chemical substances or forms of energy; modification of diet, daily routine or service delivery; alteration of environment; observation; administration of questionnaires or tests; interviews; randomization of subjects; review of records, or surgical interventions. [Guidebook, 2001.]

Intervention: Physical procedures by which data are gathered (for example, venipuncture) or manipulations of the subject or subject's environment are performed for research purposes. [WPU-IRB Policy, 1996.]

Interaction: Communication or interpersonal contact between investigator and subject. [WPU-IRB Policy, 1996.]

Surveys: Studies designed to obtain information from a large number of respondents through written questionnaires, in-person interviews, telephone interviews, door-to-door canvassing, or similar procedures. [Guidebook, 2001.]

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." [Guidebook, 2001.]

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Common Rule, 46 CFR 45.102(i)]. Examples: The risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. [Guidebook, 2001.] The risk of asking questions concerning a persons life history or experience purposes no greater risk than having a conversation on the same topic.

Adverse Effect: An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy). [Guidebook, 2001.]

2. Researchers and Officials

Principal Investigator: The scientist or scholar with primary responsibility for the design and conduct of a research project. [Guidebook, 2001.]

Investigator or Researcher: An individual who actually conducts an investigation or study [21 CFR 312.3;. Guidebook, 2001.]

Research Project Staff: Other project staff involved in the conduct of a research project. Unlike an Investigator or the Principal Investigator, project staff have little direct contact with subjects but may have extensive contact with the data generated through the research. [Guidebook, 2001.]

Legally Authorized Representative: A person authorized either by statute or by court appointment to make decisions on behalf of another person; a guardian. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [Common Rule, 46 CFR 45.102(c)].

Authorized Institutional Official or Responsible Institutional Official: An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research. [Guidebook, 2001.]

Institutional Review Board or IRB: A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research [Common Rule, 46 CFR 45.102(g), ___.108, ___.109].

IRB Chair: The person elected by the IRB Committee to work with the Authorized Institutional Official and the IRB Administrator to achieve the effective implementation of IRB-related policies and regulations.

IRB Administrator: An official of an institution with the responsibility to (a) insure the effective implementation of IRB-related policies and regulations, (b) support the activities of the Authorized Institutional Official, the IRB Committee and the IRB Chair, (c) maintain well organized and accessible records on IRB Committee activities and meetings, reviewed protocols, and related information, and (d) distribute information to the local community to improve and ensure compliance with all appropriate policies and regulations.

3. Research Subjects

Human Subjects: Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [Common Rule, 46 CFR 45.102(f)].

Classes of Subjects

Normal Volunteers: Volunteer subjects used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as comparisons with subjects who do have the condition. "Normal" may not mean normal in all respects. Example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism and patients with heart disease but without diabetes may be "normal" for a study of diabetes complicated by heart disease. [Guidebook, 2001.]

Patient: A sick individual, especially when awaiting or under the care and treatment of a health care professional, a hospital, clinic, nursing home or other medical facility, or a client of a health care professional, hospital, clinic or health care provider, or a resident of hospital, nursing home or other medical facility. See also Cognitively Impaired Person. [Guidebook, 2001.]

Cognitively Impaired Person: Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. [Guidebook, 2001.]

Institutionalized Cognitively Impaired: Persons who are confined, either voluntarily or involuntarily, in a facility for the care of the mentally or otherwise disabled (e.g., a psychiatric hospital, home, or school for the retarded). [Guidebook, 2001.]

Elderly/Aged Person: An individual who is at least 65 years old. [Guidebook, 2001.]

Minority: An individual of African, Asian, Hispanic, Native American or other ancestry as designed by William Paterson University, other cognizant agencies, or a prospective funding agency.

Students: Individuals who are enrolled in an educational institution, including William Paterson University, regardless of their age, course of study, level of enrollment (e.g: full or part time) or other factor.

Employees: An individual paid by a company or entity for work they do on behalf of that company or entity, including William Paterson University, and regardless of their age, work assignment, level of employment (e.g: full or part time) or other factor. For the purposes of this policy, includes consultants.

Federally identified "Vulnerable Populations."

Fetus: The product of conception from the time of implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant [45 CFR 46.203(c)]. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development. [Guidebook, 2001.] A Dead Fetus is an expelled or delivered fetus that exhibits no heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord (if still attached) [45 CFR 46.203(f)]. Fetal Material or Tissue: The placenta, amniotic fluid, fetal membranes, and umbilical cord [Guidebook, 2001.] A Nonviable Fetus is an expelled or delivered fetus which, although it is living, cannot possibly survive to the point of sustaining life independently, even with the support of available medical therapy [45 CFR 46.203 (d) and (e)].

Neonate: Neonate means a newborn [45 CFR 46.102(d)]. A nonviable neonate means a neonate after delivery that, although living, is not viable [45 CFR 46.102(e)]. A Viable Infant is a delivered or expelled fetus, the term "viable infant" means likely to survive to the point of sustaining life independently, given the benefit of available medical therapy [45 CFR 46.202(d)].

Woman: An individual who, as it pertains to The Common Rule's concerns for fetuses and neonates, bears young or produces eggs as distinguished from one that produces sperm.

Pregnancy: For women, the period of time from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). Implantation is confirmed through a presumptive sign of pregnancy such as missed menses or a positive pregnancy test [45 CFR 46.203(b)]. This "confirmation" may be in error, but, for research purposes, investigators would presume that a living fetus was present until evidence to the contrary was clear. Although fertilization occurs a week or more

before implantation, the current inability to detect the fertilization event or the presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary. [Guidebook, 2001.]

Children: Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)]. The age of consent or majority in New Jersey is 16.

Mature Minor: Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care). Note that a mature minor is not necessarily an emancipated minor. [Guidebook, 2001.]

Prisoner: An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statue; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)].

4. Review Process and Considerations

Assent: Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. [Guidebook, 2001.]

Assurance: A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [Common Rule, 46 CFR 45.103].

Confidentiality: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. [Guidebook, 2001.]

Consent, See: Informed Consent.

Informed Consent: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy 116; 21 CFR 50.20 and 50.25].

Permission: The agreement of parent(s) or legally authorized representative(s) (i.e.: guardian) to the participation of their child or ward in research [45 CFR 46.402(c)].

Private information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects (i.e., the identity of the subject or his or her membership in an identifiable group that may be isolated by the information collected may readily be ascertained by the investigator, the subject or other individuals). [WPU-IRB Policy, 1996.]

Protocol: The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data. The protocol may include therapeutic or other activities intended to benefit the subjects and procedures, as well as procedures to evaluate such activities. [Guidebook, 2001.]

Review (of Research): The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis [Common Rule, 46 CFR 45.108(e)].

Voluntary: Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity. [Guidebook, 2001.]

Types of Reviews

Initial Review: The first time an Institutional Review Board reviews and takes an action on a research protocol. The initial review period continues until the protocol is approved. The three types of initial reviews include Exempted Review (the review of certain kinds of research involving no risk and for minor changes in approved research [Common Rule, 46 CFR 45.110]), Expedited Review (the review of certain kinds of research involving no more than minimal risk and for minor changes in approved research [Common Rule, 46 CFR 45.110]), and Full Board Review (the review of all research that is not otherwise exempted or expedited [Common Rule, 46 CFR 45.108]).

Continuing Review: All reviews subsequent to a protocol's approval. Includes the the reevaluation of research projects at intervals appropriate to the degree of risk but not less than once a year [Common Rule, 46 CFR 45.108(e)], substantive changes to the approved protocol, the reporting of adverse reactions or unanticipated findings [Guidebook, 2001], and the termination of the study.

Student Protocol Review: The review of proposed research by a WPU undergraduate or graduate student that includes one of four key factors (the study involves a vulnerable population, collection of sensitive information, poses more than minimal physical or psychological risk to subject or student investigator, or collects identifying information on subjects) or is required by the academic department or instructor for completion of the course.[WPU-IRB Policy, 1999 revision.]

5. Policies

The Nuremburg Code: A code of conduct concerning the use of human subjects in research that resulted from the war crime trials following World War II.

The Declaration of Helsinki: Published by the World Medical Association; defines how the principals of "The health of a patient is a doctor's first consideration" are applied to research involving human subjects.

The Belmont Report: A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978. [Guidebook, 2001.] The three guiding principals defined in the Belmont Report are:

> BENEFICENCE: An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.
>
> JUSTICE: An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.
>
> RESPECT FOR PERSONS An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

The Common Rule or 45 CFR Part 46, the Federal Regulations that govern research conducted in the United States that is funded or supported through the Department of Health & Human Services and 17 other Federal Agencies and Departments.

21 CFR Part 50: Regulations governing research involving human subjects funded, supported or applying to the Food and Drug Administration. This is very similar to The Common Rule but differing in several important ways concerning clinical trials and the introduction of new drugs and devices.